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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,797	04/17/2001	Henry C. Lin	(18810-81652)	9913

7590 02/09/2004

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EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/837,797	<b>Applicant(s)</b> LIN ET AL.	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

**-- Th MAILING DATE of this communication appears on the cover sheet with th correspond nce address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2003, 12 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 46-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                                 |                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/14, 2/10</u> . | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 14 July 2003, paper #12, is acknowledged. Claims 1-20 have been canceled. New claims 46-85 have been added.
2. Applicants' Power of Attorney, received 12 January 2004, is acknowledged
3. Claims 46-85 are pending and under consideration.

### **Rejection Moot**

4. The rejection of claims 1-20 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of SIBO in irritable bowel syndrome patients with a predigested nutritional formula VIVONEX<sup>®</sup> alone, does not reasonably provide enablement for treatment of SIBO or other SIBO caused conditions by deprivation of all/some nutrients or single nutrient nor of combination therapies with enzymes, absorption alterations, or any other therapies, is moot in light of the cancellation of the claims.

### **Double Patenting**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 46-85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 09/374,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 12 of copending Application No. 09/374,142 recites a method of treating irritable bowel syndrome comprising detecting the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome and at least partially eradicating the bacterial overgrowth, whereby the at least one symptom is improved. The instant claim 46 recites a method of treating small intestinal bacterial overgrowth caused irritable bowel syndrome in a human subject, comprising detecting in the subject the presence of small intestinal bacterial overgrowth and depriving the population of bacteria of nutrients sufficiently to at least partially eradicate small intestinal bacterial overgrowth in the subject.

Thus, both sets of claims are drawn to treating irritable bowel syndrome by first detecting small intestinal bacterial overgrowth in a human subject and at least partially eradicating the small intestinal bacterial overgrowth. Claim 12 of copending Application No. 09/374,142 is drawn to any method of eradicating the small intestine overgrowth to treat irritable bowel syndrome and as such encompasses the instant claims which are drawn to one type of method, i.e., nutrient deprivation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 46-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of SIBO in irritable bowel syndrome patients with a predigested nutritional formula VIVONEX® alone, does not reasonably provide enablement for treatment of SIBO or other SIBO caused conditions by deprivation of all/some nutrients or single nutrient nor of combination therapies with enzymes, absorption alterations, or any other therapies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - method of treating SIBO or a SIBO caused condition in a human subject, said method comprising: 1) detecting SIBO, and if SIBO is present, 2) depriving the bacterial population of nutrients sufficiently to inhibit the growth of said bacterial and thereby partially eradicating SIBO in said subject.

The state of the prior art indicates that SIBO is detectable in a variety of afflictions of mammals. Therapy includes surgery, diet changes (in dogs and cats), and/or antibiotic therapy to reduce the level of SIBO. Nutritional requirements of bacteria found in SIBO is well-known. However, the ability to alter the bacterial levels in SIBO through diet alone by depriving the bacteria of an essential nutrient or nutrients is not well known.

The amount of direction or guidance present - The instant specification provides only one example of the claimed nutrient deprivation method, i.e., example 11, which uses a commercially available composition, VIVONEX®, which comprises many predigested nutrients. All of the patients involved in the study are diagnosed with irritable bowel syndrome. No other patients with other diagnosis are included. There are no examples of single nutrient deprivation being successful for treating SIBO, nor is there guidance for determining which single nutrients would be successful. The example does not provide evidence that any conditions of the patients other than reduction in SIBO have been altered.

The quantity of experimentation necessary to fulfill the scope of the instant claims constitutes merely an invitation to experiment, without a reasonable expectation of success in determining what single nutrient treats SIBO.


### **Conclusion**

9. No claims are allowed.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER

Art Unit 1645

February 3, 2004